REMARKS

Claims 14-18, 23-30 and 32-48 are pending in this application. Of these claims, 16-18, 30 and 32-48 have been previously withdrawn from consideration and claims 1-13, 19-22, and 31 have been previously canceled, without prejudice.

Claims 14, 15 and 23-29 stand rejected.

Claims 26, 28 and 29 have been canceled, without prejudice.

Claims 14, 23 and 27 have been amended. Support for these amendments can be found throughout the specification, as originally filed.

This response is submitted in response to a final office action. The Applicant submits that the instant response places the application in a condition for allowance, or alternatively, in better form for appeal.

37 CFR 1.75(c) OBJECTION

Claims 26 and 28 stand objected under 37 CFR §1.75(c), as being improper dependent form for failing to further limit the subject matter of a previous claim.

The Applicant respectfully traverses the objection to the claims.

In the interests of expediting prosecution of the instant application, and without admission that any amendment is required, the Applicants have canceled claims 26 and 28, without prejudice. Therefore, the 37 CFR §1.75(c) objection of claims 26 and 28 is moot.

35 USC §103(a) REJECTION

Claims 14-15 and 23-29 stand rejected under 35 USC §103(a) as being unpatentable over Dahlen et al. (WO 97/28797) in view of Katzung ("Basic & Clinical Pharmacology," 6th ed., 1995, page 312-314), both references of record, and Spector et al. (J. Allergy Clin. Immunol., 1995; 96(2): 174-181).

The Applicant respectfully traverses the 35 USC §103(a) rejection of claims 14-15 and 23-29. Claims 26, 28 and 29 have been canceled, without prejudice. Therefore, the 35 USC §103(a) rejection of claims 26, 28 and 29 is moot.

The standard for obviousness is that there must be some suggestion, either in the reference or in the relevant art, of how to modify what is disclosed to arrive at the claimed invention. In addition, "[s]omething in the prior art as a whole must suggest the desirability and, thus, the obviousness, of making" the modification to the art suggested by the Examiner. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 U.S.P.Q.2d (BNA) 1434, 1438 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988). Although the Examiner may suggest the teachings of a primary reference could be modified to arrive at the claimed subject matter, the modification is not obvious unless the prior art also suggests the desirability of such modification. *In re Laskowski*, 871 F.2d 115, 117, 10 U.S.P.Q.2d (BNA) 1397, 1398 (Fed. Cir.1989). There must be a teaching in the prior art for the proposed combination or modification to be proper. *In re Newell*, 891 F.2d 899, 13 U.S.P.Q.2d (BNA) 1248 (Fed. Cir. 1989). If the prior art fails to provide this necessary teaching, suggestion, or incentive supporting the Examiner's suggested

modification, the rejection based upon this suggested modification is error and must be reversed. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d (BNA) 1566 (Fed. Cir. 1990).

Claim 14 recites, among other things, a composition for the treatment of asthma, the composition comprising: (1) montelukast sodium; (2) an antihistamine selected from the group consisting of cetirizine, fexofenadine, and combinations thereof; and (3) a sympathomimetic bronchodilator.

Neither Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, suggests such a composition as claimed in claim 14.

The Examiner correctly noted that Dahlen does not disclose asthma compositions containing adrenergic bronchodilators such as albuterol. The Examiner also correctly noted that Dahlen does not disclose asthma compositions containing cetirizine.

While Katzung may arguably disclose that albuterol is useful in treating asthma, it is completely silent with respect to the use of albuterol in combination with both montelukast sodium and an antihistamine selected from the group consisting of cetirizine, fexofenadine, and combinations thereof. Furthermore, Katzung discloses that sympathomimetic agents, including albuterol, are potentially associated with severe reactions in patients. Thus, one of ordinary skill in the art would be hesitant to combine albuterol with other medicines absent a fairly high certainty that potentially severe side effects would not result in the combination.

Additionally, while Spector may arguably disclose that cetirizine is useful in treating asthma, it is completely silent with respect to the interchangeability of cetirizine

and loratadine. In fact, Spector does not even mention loratadine at all. Thus, the Applicant is uncertain as to the basis of the Examiner's assertion of interchangeability or substitutability. If the Examiner is relying on personal knowledge as to the alleged interchangeability of cetirizine and loratadine, then the Applicant respectfully requests an affidavit, executed by the Examiner, to that effect. Further, Spector does not appear to disclose the use of montelukast sodium for the treatment of asthma.

Furthermore, the Examiner's reliance on *In re Kerkhoven* is misplaced in that case merely dealt with detergent compositions that are used for purely external purposes, as opposed to the instant application, which is concerned with asthma compositions that are for internal use only. Thus, one of ordinary skill in the art would not think to merely combine different classes of medicinal ingredients due to the potentially fatal consequences should one class of medicine react poorly with another class or cause an allergic reaction in the subject ingesting the combined medicine.

Thus, when considering the recitation of claim 14, there does not appear to be any motivation or suggestion in Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, to develop a formulation as specifically claimed therein.

Accordingly, claim 14 is patentable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons set forth above. Furthermore, claim 15, which is dependent from and further defines claim 14, is likewise patentable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons set forth above.

Claim 23 recites, among other things, a composition for the treatment of asthma, the composition comprising: (a) a leukotriene receptor antagonist; (b) a histamine receptor antagonist selected from the group consisting of cetirizine hydrochloride, fexofenadine, and combinations thereof; and (c) an adrenergic bronchodilator.

Neither Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, suggests such a composition as claimed in claim 23.

As previously noted, the Examiner correctly noted that Dahlen does not disclose asthma compositions containing adrenergic bronchodilators such as albuterol and does not disclose asthma compositions containing cetirizine.

While Katzung may arguably disclose that albuterol is useful in treating asthma, it is completely silent with respect to the use of albuterol in combination with both leukotriene receptor antagonist (e.g., montelukast sodium) and an antihistamine selected from the group consisting of cetirizine hydrochloride, fexofenadine, and combinations thereof.

Also as previously noted, while Spector may arguably disclose that cetirizine is useful in treating asthma, it is completely silent with respect to the interchangeability of cetirizine and loratadine. In fact, Spector does not even mention loratadine at all. Thus, the Applicant is uncertain as to the basis of the Examiner's assertion of interchangeability or substitutability. If the Examiner is relying on personal knowledge as to the alleged interchangeability of cetirizine and loratadine, then the Applicant respectfully requests an affidavit, executed by the Examiner, to that effect. Further,

Spector does not appear to disclose the use of a leukotriene receptor antagonist (e.g., montelukast sodium) for the treatment of asthma.

Thus, when considering the recitation of claim 23, there does not appear to be any motivation or suggestion in Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, to develop a formulation as specifically claimed therein.

Accordingly, claim 23 is patentable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons set forth above. Furthermore, claims 24, 25 and 27, which are dependent from and further defines claim 14, are likewise patentable over Dahlen et al., Katzung, and/or Spector et al., either alone or in combination therewith, for at least the reasons set forth above.

Accordingly, the Applicant contends that the 35 USC §103(a) rejection of claims 14, 15, 23-25 and 27 has been overcome.

CONCLUSION

In view of the foregoing, the Applicant respectfully requests reconsideration and reexamination of the Application. The Applicant respectfully submits that each item raised by Examiner in the Final Office Action of October 16, 2002 has been successfully traversed, overcome or rendered moot by this response. The Applicant respectfully submits that each of the claims in this Application is in condition for allowance and such allowance is earnestly solicited.

The Examiner is invited to telephone the Applicant's undersigned attorney at (248) 364-4300 if any unresolved matters remain.

Any needed extension of time is hereby requested with the filing of this document.

The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 501612. A duplicate copy of this letter is enclosed herewith for this purpose.

Respectfully submitted,
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